

Sheet 1 of 4

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50304/112001
	Serial No.	10/556,851
	Applicant	Saint-Remy et al.
	371(c) Date	February 1, 2006
	Group	1644
	IDS Filed	February 27, 2008

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant
/MS/	US 5,602,015	Feb. 11, 1997	Sudhir
	US 5,744,446	Apr. 28, 1998	Lollar et al.
	US 6,210,675	Apr. 3, 2001	Highfield et al.
	US 7,067,313	Jun. 27, 2006	Jacquemin et al.
/MS/	2003/0175268	Sept. 18, 2003	Saint-Remy et al.

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
/MS/	EP 0 822 255 A2	Feb. 4, 1998	E.P.O.	
/MS/	WO 97/26010 A1	Jul. 24, 1997	W.I.P.O.	
/MS/	WO 01/04269 A1	Jan. 18, 2001	W.I.P.O.	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/MS/	Batile et al., "Alloantibody from a Patient with Severe von Willebrand Disease Inhibits von Willebrand Factor-FVIII Interaction," <i>Ann. Hematol.</i> 75:111-115 (1997).
	Begany, "Monoclonal Antibody Improves Sepsis" <i>Pulmonary Reviews.Com</i> Vol. 5, No. 8 (2000).
	Cobb, "Septic Polyarthritis in a Hemophiliac," <i>J. Rheumatol.</i> 11:87-89 (1984).
	Ferenz and Tozzi, "Sepsis due to an Infected Pseudocyst of Hemophilia," <i>Clin. Orthopaedics Rel. Res.</i> 244:254-257 (1989).
/MS/	Freeman et al., "The Role of Inflammation in Sepsis and Septic Shock: A Meta-Analysis of Both Clinical and Preclinical Trials of Anti-Inflammatory Therapies," <i>Inflammation: Basic Principles and Clinical Correlates</i> , 3rd Ed., Lippincott Williams & Wilkins, Philadelphia, PA, pp. 965-975 (1999).

EXAMINER /Michael Szperka/	DATE CONSIDERED 04/30/2009
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Sheet 2 of 4

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50304/112001
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/556,851
		Applicant	Saint-Remy et al.
		371(c) Date	February 1, 2006
		Group	1644
(37 C.F.R. § 1.98(b))		IDS Filed	February 27, 2008

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/MS/	Gawryl and Hoyer, "Inactivation of Factor VIII Coagulant Activity by Two Different Types of Human Antibodies," <i>Blood</i> 60:1103-1109 (1982)
	Gilles et al., "Anti-Factor VIII Antibodies of Hemophiliac Patients Are Frequently Directed Towards Nonfunctional Determinants and Do Not Exhibit Isotypic Restriction," <i>Blood</i> 82:2452-2461 (1993).
	Gilles et al., "The Arg 2150 His Mutation Within the Factor VIII C1 Domain Eliminates a B Cell Epitope that is Present Only on Factor VIII-Von Willebrand Factor Complexes," <i>Blood</i> 92(Suppl. 1):710a, Abstract 2919 (1998).
	Gilles and Saint-Remy, "Healthy Subjects Produce both Anti-Factor VIII and Specific Anti-Idiotypic Antibodies," <i>J. Clin. Invest.</i> 94:1496-1505 (1994).
	Ingerslev et al., "Applications of Immunoperoxidase Techniques in Specificity Testing of Monoclonal Antibodies (Mabs) Against Von Willebrand Factor (vWf)," <i>Clin. Chem. Acta</i> 174:65-82 (1988).
	Jacquemin et al., "Mechanism and Kinetics of Factor VIII Inactivation: Study with an IgG4 Monoclonal Antibody Derived from a Hemophilia A Patient with Inhibitor," <i>Blood</i> 92:496-506 (1998).
	Jacquemin et al., "A Human Antibody Directed to the Factor VIII C1 Domain Inhibits Factor VIII Cofactor Activity and Binding to von Willebrand Factor," <i>Blood</i> 95:156-163 (2000).
	Jacquemin et al., "Glycosylation of Type 2 Factor VIII Inhibitor Determines Its Maximum Level of FVIII Inhibition," <i>Blood</i> 102:163a (2003). Abstract Only.
	Janeway et al., "The Interaction of the Antibody Molecule with Specific Antigen," <i>Immunobiology</i> , 3 rd Ed., Garland Publishing, New York, NY, pp. 3:7-3:11 (1997).
	Janeway et al., "Germinal Center B Cells Undergo V-Region Somatic Hypermutation, and Cells With Mutations that Improve Affinity for Antigen are Selected," <i>Immunobiology</i> , 6th Ed., Garland Science Publishing, New York, NY, pp. 379-381 (2005).
	Kallas et al., "Epitope Specificity of Anti-FVIII Antibodies During Immune Tolerance Therapy With Factor VIII Preparation Containing von Willebrand Factor," <i>Thromb. Res.</i> 107:291-302 (2002).
	Kato et al., "Activity Enhancement of a Lung Cancer-Associated Human Monoclonal Antibody HB4C5 by N-Deglycosylation," <i>Hum. Antibod. Hybridomas</i> 4:9-14 (1993).
	Khurana et al., "The Variable Domain Glycosylation in a Monoclonal Antibody Specific to GnRH Modulates Antigen Binding," <i>Biochem. Biophys. Res. Comm.</i> 234:465-469 (1997).
	Lenting et al., "Identification of a Binding Site for Blood Coagulation Factor IXa on the Light Chain of Human Factor VIII," <i>J. Biol. Chem.</i> 269:7150-7155 (1994).
/MS/	Ly et al., "Characterization of an Antibody to Factor VIII in a Patient with Acquired Hemophilia with Circulating Immune Complexes," <i>Scand. J. Haematol.</i> 28:132-140 (1982).

EXAMINER /Michael Szperka/	DATE CONSIDERED 04/30/2009
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Sheet 3 of 4

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50304/112001
<p style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)</p> <p>(37 C.F.R. § 1.98(b))</p>		Serial No.	10/556,851
		Applicant	Saint-Remy et al.
		371(c) Date	February 1, 2006
		Group	1644
		IDS Filed	February 27, 2008

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/MS/	Martinell et al., "Peritonitis and Septic Shock—An Evaluation of Two Experimental Models in the Rat," <i>Eur. Surg. Res.</i> 17(3):160-166 (1985). Abstract only.
	Merck Manual of Diagnosis and Disease, 17 th Ed., Beers et al. (Eds.), Merck Research Laboratories, Whitehouse, NJ, pp. 1143-1147 (1999).
	Near et al., "Characterization of an Anti-Digoxin Antibody Binding Site by Site-Directed <i>In Vitro</i> Mutagenesis," <i>Mol. Immunol.</i> 30(4):369-377 (1993).
	Peerlinck et al., "Antifactor VIII Antibody Inhibiting Allogeneic but not Autologous Factor VIII in Patients with Mild Hemophilia A," <i>Blood</i> 93:2267-2273 (1999).
	Price et al., "Tissue Factor and Tissue Factor Pathway Inhibitor," <i>Anaesthesia</i> 59:483-492 (2004).
	Riedemann and Ward, "Anti-Inflammatory Strategies for the Treatment of Sepsis," <i>Expert Opin. Biol. Ther.</i> 3(2):339-350 (2003).
	Rudikoff et al., "Single Amino Acid Substitution Altering Antigen-Binding Specificity," <i>Proc. Natl. Acad. Sci. USA</i> 79:1979-1983 (1982).
	Saint-Remy, "B- and T-cell Tolerance: From Basic Concepts to Clinical Practice," <i>Haematologica</i> 85(Suppl. to No. 10):93-96 (2000).
	Sato et al., "Humanization of an Anti-Human IL-6 Mouse Monoclonal Antibody Glycosylated in Its Heavy Chain Variable Region," <i>Hum. Antibod. Hybridomas</i> 7(4):175-183 (1996).
	Scandella et al., "Localization of Epitopes for Human Factor VIII Inhibitor Antibodies by Immunoblotting and Antibody Neutralization," <i>Blood</i> 74:1618-1626 (1989).
	Singh et al., "Antithrombotic Effects of Controlled Inhibition of Factor VIII with a Partially Inhibitory Human Monoclonal Antibody in a Murine Vena Cava Thrombosis Model," <i>Blood</i> 99:3235-3240 (2002).
	Taylor et al., "7E3 F(ab') ₂ , a Monoclonal Antibody to the Platelet GPIIb/IIIa Receptor, Protects Against Microangiopathic Hemolytic Anemia and Microvascular Thrombotic Renal Failure in Baboons Treated With C4B Binding Protein and a Sublethal Infusion of <i>Escherichia coli</i> ," <i>Blood</i> 89:4078-4084 (1997).
	Wright et al., "Antibody Variable Region Glycosylation: Position Effects on Antigen Binding and Carbohydrate Structure," <i>EMBO J.</i> 10:2717-2723 (1991).
	Yan et al., "Therapeutic Effects of Lysophosphatidylcholine in Experimental Sepsis," <i>Nature Medicine</i> 10:161-167 (2004).
/MS/	Yelton et al., "Affinity Maturation of the BR96 Anti-Carcinoma Antibody by Codon-Based Mutagenesis," <i>J. Immunol.</i> 155:1994-2004 (1995).

EXAMINER /Michael Szperka/

DATE CONSIDERED 04/30/2009

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

Sheet 4 of 4

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50304/112001
	Serial No.	10/556,851
	Applicant	Saint-Remy et al.
	371(c) Date	February 1, 2006
	Group	1644
	IDS Filed	February 27, 2008

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/MS/	Ziegler et al., "Treatment of Gram-Negative Bacteremia and Septic Shock with HA-1A Human Monoclonal Antibody Against Endotoxin. A Randomized, Double-Blind, Placebo-Controlled Trial. The HA-1A Sepsis Study Group," <i>New Engl. J. Med.</i> 324:429-436 (1991). Abstract only.
	Written Opinion for PCT/BE2004/000118 mailed February 2, 2005.
	International Search Report for PCT/BE2004/000118 mailed February 2, 2005.
/MS/	International Preliminary Report on Patentability for PCT/BE2004/000118 dated December 2, 2005.

EXAMINER	/Michael Szperka/	DATE CONSIDERED	04/30/2009
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.			